UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

July 30, 2015

MEMORANDUM

Subject: Efficacy Review for CDG Solution 3000; EPA Reg. no. 75757-2; DB Barcode: D426981.

From: Ibrahim Laniyan, Ph.D.
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Thru: Mark Perry, Team Leader
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To: Demson Fuller RM32
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: CDG Environmental LLC
759 Roble Road
Allentown, PA 18109

Formulation from the Label:

Active Ingredient	% by wt.
Chlorine dioxide	0.30 %
Other Ingredients:	99.70 %
Total	100.00 %

CDG Solution 3000™ contains 3000 ppm (3000 mg/liter) chlorine dioxide

I. BACKGROUND

The product, CDG Solution 3000 (EPA Reg. no. 75757-2), is an EPA-approved disinfectant that employs chlorine dioxide to purify water for animal and human consumption. Per the label, this product is designed to purify potable water including hospital and cruise ship water systems, potable water for human consumption, and water for livestock. The applicant is submitting current makes the following changes to the product label

1. Addition of claim for use as sanitizing rinse on previously cleaned, food-contact surfaces;
2. Duplication of existing claim against *Klebsiella terrigena*, Poliovirus and Rotavirus throughout the label;
3. Addition of claim for, "Treatment for red meat including parts and organs, ready to eat meats or formed meats" with associated FCN;
4. Addition of claim for use of product as a fruit and vegetable wash;
5. Clarification of term "slime-forming algae";
6. Addition of phrase, "Not for use in California" to several use sites;
7. Addition of reference to product brochure.

Study was conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package, identified as D426981, contained a letter from the applicant representative to EPA (dated March 13, 2015), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), one study (MRID Nos. 495831-01), Statements of No Data Confidentiality Claims for study, and the proposed label.

II. USE DIRECTIONS

CDG Solution 3000 is a chlorine dioxide product designed to purify water which has previously been treated in accordance with the Safe Drinking Water Act (SDWA) including: potable water and cooling water in hospitals & healthcare facilities, nursing homes, hotels, commercial office buildings, government buildings, residential buildings, and ships; industrial process water; food processing water; livestock drinking water. *CDG Solution 3000* also is designed to control slime in cooling towers. Pathogenic organisms controlled include *Klebsiella terrigena*, Poliovirus and Rotavirus. Concentration and contact times are application specific. Minimum contact time for control of listed pathogenic organisms is 5 minutes.

SANITIZING SOLUTION FOR FOOD CONTACT SURFACES
Prior to sanitization, remove all gross food particles and soil by use of a pre-flush, pre-scrape or pre-soak treatment. Prepare a maximum 50 ppm solution of CDG Solution 3000 by using a dilution ratio of 60:1. Using a commercial sprayer, saturate all surfaces with the diluted CDG Solution 3000. Allow surfaces to remain wet for at least 1 minute. The diluted CDG Solution 3000 may be irritating if inhaled. For spraying operations, user must wear a half-face respirator with acid gas cartridge and N95 filter. This product is effective against *Salmonella enterica* serovar Typhi (ATCC 6539) and *Staphylococcus aureus* (ATCC 6538).

Human water systems

TREATMENT OF POTABLE WATER FOR HUMAN CONSUMPTION

For most municipal and other potable water systems, add *CDG Solution 3000* to the water at a dose of up to 2.0 ppm (2.0 mg/L) chlorine dioxide (a dilution ratio 1500:1). **Under US EPA regulations, drinking water intended for human consumption may not contain more than 0.8 ppm (0.8 mg/liter) residual chlorine dioxide no more than 1.0 ppm (1.0 mg/liter) chlorite ion.** This product is effective against Klebsiella terrigena, Poliovirus and Rotavirus.

WATER STORAGE SYSTEMS ABOARD AIRCRAFT BOATS, RV'S AND OFF-SHORE OIL RIGS

Add *CDG Solution 3000* to the water at a dose of up to 2.0 ppm (2.0 mg/L) chlorine dioxide (a dilution ratio 1500:1). **Under US EPA regulations, drinking water intended for human consumption may not contain more than 0.8 ppm (0.8 mg/liter) residual chlorine dioxide no more than 1.0 ppm (1.0 mg/liter) chlorite ion.** This product is effective against Klebsiella terrigena, Poliovirus and Rotavirus.

MUNICIPAL WELL WATERS

For most municipal water systems, add *CDG Solution 3000* to the water at a dose of up to 1.0 ppm (1.0 mg/L) chlorine dioxide (a dilution ratio 3000:1). **Under US EPA regulations, drinking water intended for human consumption may not contain more than 0.8 ppm (0.8 mg/liter) residual chlorine dioxide no more than 1.0 ppm (1.0 mg/liter) chlorite ion.** This product is effective against Klebsiella terrigena, Poliovirus and Rotavirus.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Sanitizing Rinses (For Previously Cleaned Food Contact Surfaces): Sanitizing rinses may be formulated with iodophors, mixed halides, or chlorine-bearing chemicals, among other active ingredients. The effectiveness of halide sanitizing rinses for previously cleaned food contact surfaces must be substantiated by data derived from the AOAC International Chlorine (Available) in Disinfectants Germicidal Equivalent Concentration test. Data from one test on each of 3 product samples, representing 3 different batches at the LCL, against *Salmonella enterica* (ATCC 6539) or *Staphylococcus aureus* (ATCC 6538). **Performance standard:** Test results must show product concentrations equivalent in activity to 50, 100, and 200 ppm of available chlorine. The reference standard is sodium hypochlorite. These Agency standards are presented in OCSPP 810.2300.

IV. BRIEF DESCRIPTION OF THE DATA

Note: The tested active ingredients concentrations of 131106-2, 131108-3 131111-1 were diluted to lower than the required LCL concentration.

> **1. MRID 495831-01 "AOAC Available Chlorine in Disinfectants, Test Organism: *Salmonella enterica* serovar Typhi (ATCC 6539) and *Staphylococcus aureus* (ATCC 6538)" for CDG Solution 3000™, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – January 7, 2014. Project Number A15892.**

This study was conducted against *Salmonella enterica* serovar Typhi (ATCC 6539) and *Staphylococcus aureus* (ATCC 6538) grown in nutrient broth. Two lots (131106-2, 131108-3 131111-1) of the product, CDG Solution 3000™, were tested according to ATS Labs Protocol No. WES20091313.AVC (copy provided). The product was diluted 1:133 (0.96 oz./gallon defined as 0.96 oz. test substance + 127.04 oz. 300 ppm AOAC synthetic hard water). Sodium hypochlorite

(NaOCl) was used as the data control standard at three concentrations, 200 ppm (titrated at 200 ppm), 100 ppm, and 50 ppm. Letheen Broth with 0.1% Sodium Thiosulfate was used as neutralizer; and Tryptic Soy Agar with 5% sheep blood was used as agar plate medium. A 0.05 ml aliquot of the test culture was added to each (10 ml) of the test substance and control NaOCl solutions at 20±1°C. One minute after addition of the test organism, 10 µl of each medicated culture was transferred to the subculture medium. Each tube was then challenged with additional 0.05 ml aliquot of the test culture 30 seconds after subculturing. This process was repeated for a total of 10 subcultures for each lot and control. The neutralized subcultures were incubated for 48±2 hours at 35-37°C and examined for the presence or absence of visible growth. Representative neutralized subcultures showing growth were subcultured, stained and/or biochemically assayed to confirm or rule out the presence of the test organism. Controls included neutralization, viability control, purity, initial suspension population and sterility. The reported colony forming units per ml in the initial suspension population is ***Salmonella typhi* 4.7 x 10^8** and ***Staphylococcus aureus* 1.5 x 10^8.**

V. RESULTS

MRID # 495831-01

Organism	Test/Control Substance	Concentration or Lot	Subculture Number									
			1	2	3	4	5	6	7	8	9	10
Salmonella enterica serovar Typhi (ATCC 6539)	NaOCl Control	200 ppm	0	0	0	0	0	0	0	+	+	+
		100 ppm	0	0	0	0	+	+	+	+	+	+
		50 ppm	0	0	+	+	+	+	+	+	+	+
	CDG Solution 3000™	Batch 131106-2	0	0	0	0	0	0	+	+	+	+
		Batch 131108-3	0	0	0	0	0	0	0	+	+	+
		Batch 131111-1	0	0	0	0	0	0	0	+	+	+
Staphylococcus aureus (ATCC 6538)	NaOCl Control	200 ppm	0	0	0	0	0	0	0	+	+	+
		100 ppm	0	0	0	+	+	+	+	+	+	+
		50 ppm	0	0	+	+	+	+	+	+	+	+
	CDG Solution 3000™	Batch 131106-2	0	0	0	0	0	0	0	0	+	+
		Batch 131108-3	0	0	0	0	0	0	0	+	+	+
		Batch 131111-1	0	0	0	0	0	0	0	+	+	+

VI. CONCLUSION

1. The submitted efficacy data (MRID 495831-01) **support** the use of the product, CDG Solution 3000™ (EPA Reg. no. 75757-2), as a food contact sanitizer when diluted 1:133 in 300 ppm hard water (equivalent to 200 ppm NaOCl), at room temperature, for 1 minute contact time.

VII. LABEL

1. The proposed label claims **are acceptable** regarding the use of the product, CDG Solution 3000™ (EPA Reg. no. 75757-2), as an effective food contact sanitizer when diluted 1:60 (50 ppm chlorine dioxide), at room temperature, for 1 minute contact time.

2. Previously submitted efficacy studies (MRID nos. 47047901, 47047902, and 47047903) for *Klebsiella terrigena*, *Legionella pneumophilia,* Poliovirus, and Rotavirus were conducted at 1.5

ppm chlorine dioxide concentration for 5 minutes contact time. The followings are the required changes to the proposed label:

a) TREATMENT OF POULTRY DRINKING WATER: If the water supply has heavy contamination, prepare a solution of 5.0 ppm available chlorine dioxide by adding CDG Solution 3000 to water at a dose of 5.0 ppm (5.0 mg/liter) chlorine dioxide (a dilution ratio 600:1). Allow 15 minutes before delivery to poultry. This product is effective against *Klebsiella terrigena*, Poliovirus and Rotavirus. After 24 hours, the addition rate can be reduced to 1 ppm chlorine dioxide by adding CDG Solution 3000 to water at a dose of 1 mg/liter chlorine dioxide (a dilution ratio 3000:1) as long as terminal concentration at end of waterline is not less than 0.5 ppm. Treat water continuously from day one. Remove CDG Solution 3000 from drinking water 24 hours prior to vaccination, then resume treatment 24 hours after vaccinations.

b) TREATMENT OF POTABLE WATER FOR HUMAN CONSUMPTION: For most municipal and other potable water systems, add *CDG Solution 3000* to the water at a dose of 1.5 ppm (1.5 mg/L) up to 2.0 ppm (2.0 mg/L) chlorine dioxide (a dilution ratio 1500:1). This product is effective against Klebsiella terrigena, Poliovirus and Rotavirus. **Under US EPA regulations, drinking water intended for human consumption may not contain more than 0.8 ppm (0.8 mg/liter) residual chlorine dioxide no more than 1.0 ppm (1.0 mg/liter) chlorite ion.**

c) WATER STORAGE SYSTEMS ABOARD AIRCRAFT BOATS, RV'S AND OFF-SHORE OIL RIGS: Add *CDG Solution 3000* to the water at a dose of 1.5 ppm (1.5 mg/L) up to 2.0 ppm (2.0 mg/L) chlorine dioxide (a dilution ratio 1500:1). This product is effective against Klebsiella terrigena, Poliovirus and Rotavirus. **Under US EPA regulations, drinking water intended for human consumption may not contain more than 0.8 ppm (0.8 mg/liter) residual chlorine dioxide no more than 1.0 ppm (1.0 mg/liter) chlorite ion.**

d) MUNICIPAL WELL WATERS: For most municipal water systems, add *CDG Solution 3000* to the water at a dose of up to 1.0 ppm (1.0 mg/L) chlorine dioxide (a dilution ratio 3000:1). **Under US EPA regulations, drinking water intended for human consumption may not contain more than 0.8 ppm (0.8 mg/liter) residual chlorine dioxide no more than 1.0 ppm (1.0 mg/liter) chlorite ion.** ~~This product is effective against Klebsiella terrigena, Poliovirus and Rotavirus.~~